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#19

OCT 20 1989

George R. Pepper
Bernard, Rothwell and Brown
1700 K Street, NW
Washington, DC 20006

Re: Patent Term Extension
Application for
U.S. Patent No. 4,396,598
Issued August 2, 1983

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,396,598, issued August 2, 1983 is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be 815 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on April 4, 1989 as follows:

$$\begin{aligned}\text{Period} &= 1/2 \text{ (Testing Phase)} + \text{Approved Phase} \\ &= 1/2 (521) + 554 \\ &= 815 \text{ days}\end{aligned}$$

Since the regulatory review period took place after the patent issue date and there was no determination of a lack of due diligence, the entire period has been considered. The exception of 35 USC 156(c)(3) does not operate to reduce the period determined above, nor do the limitations of 35 USC 156(g)(6)(C). The period of extension calculated under 35 USC 156(c) for Patent No. 4,396,598 and Optiray is 815 days.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent 4,396,598 may be made if filed within one (1) month of the date of this notice. This period is not subject to an extension of time under 37 CFR 1.136(a). In the absence of such request, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,398,598 a certificate of extension, under

seal, for a period of 815 days. The rights derived from the patent during the period during which the patent is extended are defined in 35 USC 156(b).

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent 4,396,598, granted August 2, 1983 to
Youlin Lin,
Owner of Record: Mallinckrodt, Inc.
Title: TRIIODOISOPHTHALAMIDE X-RAY CONTRAST AGENT
Classification: 166-85
Product Trade Name: Optiray
Term Extended: 815 days

C. E. Van Horn

Charles E. Van Horn
Office of the Assistant Commissioner
for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Optiray
FDA Docket # 89E-0055